CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER for: 020778, S011

ADMINISTRATIVE DOCUMENTS and CORRESPONDENCE

EXCLUSIVITY SUMMARY FOR NDAs # 20778/79 SUPPL # 011/022

Trade Name Viracept® Generic Name nelfinavir

Applicant Name Glaxo Wellcome HFD # 530

Approval Date If Known _____

PART I IS AN EXCLUSIVITY DETERMINATION NEEDED?

1. An exclusivity determination will be made for all original applications, but only for certain supplements. Complete PARTS II and III of this Exclusivity Summary only if you answer "yes" to one or more of the following question about the submission.

a) Is it an original NDA?

YES // NO /X/

b) Is it an effectiveness supplement?

YES /X/ NO /___/

If yes, what type? (SE1, SE2, etc.) SE2

c) Did it require the review of clinical data other than to support a safety claim or change in labeling related to safety? (If it required review only of bioavailability or bioequivalence data, answer "no.")

YES /X/ NO /___/

If your answer is "no" because you believe the study is a bioavailability study and, therefore, not eligible for exclusivity, EXPLAIN why it is a bioavailability study, including your reasons for disagreeing with any arguments made by the applicant that the study was not simply a bioavailability study.

_____

_____

If it is a supplement requiring the review of clinical data but it is not an effectiveness supplement, describe the change or claim that is supported by the clinical data:

d) Did the applicant request exclusivity?

YES // NO /X/

If the answer to (d) is "yes," how many years of exclusivity did the applicant request?

e) Has pediatric exclusivity been granted for this Active Moiety?

No, studies are ongoing.

IF YOU HAVE ANSWERED "NO" TO ALL OF THE ABOVE QUESTIONS, GO DIRECTLY TO THE SIGNATURE BLOCKS ON PAGE 8.

2. Has a product with the same active ingredient(s), dosage form, strength, route of administration, and dosing schedule, previously been approved by FDA for the same use? (Rx to OTC switches should be answered NO-please indicate as such)

YES /X/ NO //

If yes, NDA # 20778/79. Drug Name Viracept (nelfinavir) .

IF THE ANSWER TO QUESTION 2 IS "YES," GO DIRECTLY TO THE SIGNATURE BLOCKS ON PAGE 8.

3. Is this drug product or indication a DESI upgrade?

YES // NO //

IF THE ANSWER TO QUESTION 3 IS "YES," GO DIRECTLY TO THE SIGNATURE BLOCKS ON PAGE 8 (even if a study was required for the upgrade).

PART II FIVE-YEAR EXCLUSIVITY FOR NEW CHEMICAL ENTITIES

(Answer either #1 or #2 as appropriate)

1. Single active ingredient product.

Has FDA previously approved under section 505 of the Act any drug product containing the same active moiety as the drug under consideration? Answer "yes" if the active moiety (including other esterified forms, salts, complexes, chelates or clathrates) has been previously approved, but this particular form of the active moiety, e.g., this particular ester or salt (including salts with hydrogen or coordination bonding) or other non-covalent derivative (such as a complex, chelate, or clathrate) has not been approved. Answer "no" if the compound requires metabolic conversion (other than deesterification of an esterified form of the drug) to produce an already approved active moiety.

YES /_/ NO //

If "yes," identify the approved drug product(s) containing the active moiety, and, if known, the NDA #(s).

NDA#

NDA#

2. Combination product.

If the product contains more than one active moiety(as defined in Part II, #1), has FDA previously approved an application under section 505 containing any one of the active moieties in the drug product? If, for example, the combination contains one never-before-approved active moiety and one previously approved active moiety, answer "yes." (An active moiety that is marketed under an OTC monograph, but that was never approved under an NDA, is considered not previously approved.)

YES /___/ NO //

If "yes," identify the approved drug product(s) containing the active moiety, and, if known, the NDA #(s).

NDA# _____ _____

NDA# _____ _____

NDA# _____ _____

IF THE ANSWER TO QUESTION 1 OR 2 UNDER PART II IS "NO," GO DIRECTLY TO THE SIGNATURE BLOCKS ON PAGE 8. IF "YES" GO TO PART III.

PART III THREE-YEAR EXCLUSIVITY FOR NDA'S AND SUPPLEMENTS

To qualify for three years of exclusivity, an application or supplement must contain "reports of new clinical investigations (other than bioavailability studies) essential to the approval of the application and conducted or sponsored by the applicant." This section should be completed only if the answer to PART II, Question 1 or 2 was "yes."

1. Does the application contain reports of clinical investigations? (The Agency interprets "clinical investigations" to mean investigations conducted on humans other than bioavailability studies.) If the application contains clinical investigations only by virtue of a right of reference to clinical investigations in another application, answer "yes," then skip to question 3(a). If the answer to 3(a) is "yes" for any investigation referred to in another application, do not complete remainder of summary for that investigation.

YES // NO /___/

IF "NO," GO DIRECTLY TO THE SIGNATURE BLOCKS ON PAGE 8.

2. A clinical investigation is "essential to the approval" if the Agency could not have approved the application or supplement without relying on that investigation. Thus, the investigation is not essential to the approval if 1) no clinical investigation is necessary to support the supplement or application in light of previously approved applications (i.e., information other than clinical trials, such as bioavailability data, would be sufficient to provide a basis for approval as an ANDA or 505(b)(2) application because of what is already known about a previously approved product), or 2) there are published reports of studies (other than those conducted or sponsored by the applicant) or other publicly available data that independently would have been sufficient to support approval of the application, without reference to the clinical investigation submitted in the application.

(a) In light of previously approved applications, is a clinical investigation (either conducted by the applicant or available from some other source, including the published literature) necessary to support approval of the application or supplement?

YES / / NO /___/

If "no," state the basis for your conclusion that a clinical trial is not necessary for approval AND GO DIRECTLY TO SIGNATURE BLOCK ON PAGE 8:

_____

(b) Did the applicant submit a list of published studies relevant to the safety and effectiveness of this drug product and a statement that the publicly available data would not independently support approval of the application?

YES // NO /___/

(1) If the answer to 2(b) is "yes," do you personally know of any reason to disagree with the applicant's conclusion? If not applicable, answer NO.

YES /___/ NO //

If yes, explain:

(2) If the answer to 2(b) is "no," are you aware of published studies not conducted or sponsored by the applicant or other publicly available data that could independently demonstrate the safety and effectiveness of this drug product?

YES /___/ NO //

If yes, explain:

(c) If the answers to (b)(1) and (b)(2) were both "no," identify the clinical investigations submitted in the application that are essential to the approval:

AG1343-542

Studies comparing two products with the same ingredient(s) are considered to be bioavailability studies for the purpose of this section.

3. In addition to being essential, investigations must be "new" to support exclusivity. The agency interprets "new clinical investigation" to mean an investigation that 1) has not been relied on by the agency to demonstrate the effectiveness of a previously approved drug for any indication and 2) does not duplicate the results of another investigation that was relied on by the agency to demonstrate the effectiveness of a previously approved drug product, i.e., does not redemonstrate something the agency considers to have been demonstrated in an already approved application.

a) For each investigation identified as "essential to the approval," has the investigation been relied on by the agency to demonstrate the effectiveness of a previously approved drug product? (If the investigation was relied on only to support the safety of a previously approved drug, answer "no.")

Investigation #1 YES /___/ NO //

Investigation #2 YES /___/ NO //

If you have answered "yes" for one or more investigations, identify each such investigation and the NDA in which each was relied upon:

_____ _____

_____ _____

b) For each investigation identified as "essential to the approval", does the investigation duplicate the results of another investigation that was relied on by the agency to support the effectiveness of a previously approved drug product?

Investigation #1 YES /___/ NO //

Investigation #2 YES /___/ NO //

If you have answered "yes" for one or more investigation, identify the NDA in which a similar investigation was relied on:

_____ _____

_____ _____

c) If the answers to 3(a) and 3(b) are no, identify each "new" investigation in the application or supplement that is essential to the approval (i.e., the investigations listed in #2(c), less any that are not "new"):

AG1343-542

4. To be eligible for exclusivity, a new investigation that is essential to approval must also have been conducted or sponsored by the applicant. An investigation was "conducted or sponsored by" the applicant if, before or during the conduct of the investigation, 1) the applicant was the sponsor of the IND named in the form FDA 1571 filed with the Agency, or 2) the applicant (or its predecessor in interest) provided substantial support for the study. Ordinarily, substantial support will mean providing 50 percent or more of the cost of the study.

a) For each investigation identified in response to question 3(c): if the investigation was carried out under an IND, was the applicant identified on the FDA 1571 as the sponsor?

Investigation #1 !

IND # YES /___/ ! NO /___/ Explain: _____
!
!

Investigation #2 !
!

IND # _____ YES /___/ ! NO /___/ Explain: _____

(b) For each investigation not carried out under an IND or for which the applicant was not identified as the sponsor, did the applicant certify that it or the applicant's predecessor in interest provided substantial support for the study?

Investigation #1 !
!

YES /___/ Explain _____ ! NO /___/ Explain N/A
!

_____ ! _____
!

_____ ! _____
!
!

Investigation #2 !
!

YES /___/ Explain _____ ! NO /___/ Explain N/A
!

_____ ! _____
!

_____ ! _____

(c) Notwithstanding an answer of "yes" to (a) or (b), are there other reasons to believe that the applicant should not be credited with having "conducted or sponsored" the study? (Purchased studies may not be used as the basis for exclusivity. However, if all rights to the drug are purchased (not just studies on the drug), the applicant may be considered to have sponsored or conducted the studies sponsored or conducted by its predecessor in interest.)

YES /___/ NO /___/

If yes, explain: _____

_____

APPEARS THIS WAY
ON ORIGINAL

Signature /S/ Date 11-23-99
Title: Regulatory Project Officer

Signature of Office/Division Director /S/ Date 11/23/99

cc: Original NDA Division File HFD-93 Mary Ann Holovac

APPEARS THIS WAY
ON ORIGINAL

PEDIATRIC PAGE

(Complete for all original applications and all efficacy supplements)

NDA/PLA/PMA # 20-778 20-779 Supplement # S-011, S-022 Circle one: SE1 (SE2) SE3 SE4 SE5 SE6

HFD-530 Trade and generic names/dosage form: Viracept (nelfinavir) Action: AP AE NA

Applicant Agouron Laboratories, Inc Therapeutic Class 7030140 Antiviral – AIDS-Systemic.

Indication(s) previously approved: none.

Pediatric information in labeling of approved indication(s) is adequate ___ inadequate ___

Indication in this application Treatment of HIV.

___ 1. **PEDIATRIC LABELING IS ADEQUATE FOR ALL PEDIATRIC AGE GROUPS.** Appropriate information has been submitted in this or previous applications and has been adequately summarized in the labeling to permit satisfactory labeling for all pediatric age groups. Further information is not required.

___ 2. **PEDIATRIC LABELING IS ADEQUATE FOR CERTAIN AGE GROUPS.** Appropriate information has been submitted in this or previous applications and has been adequately summarized in the labeling to permit satisfactory labeling for certain pediatric age groups (e.g., infants, children, and adolescents but not neonates). Further information is not required.

X 3. **PEDIATRIC STUDIES ARE NEEDED**. There is potential for use in children, and further information is required to permit adequate labeling for this use.

___ a. A new dosing formulation is needed, and applicant has agreed to provide the appropriate formulation.

___ b. A new dosing formulation is needed, however the sponsor is either not willing to provide it or is in negotiations with FDA.

X c. The applicant has committed to doing such studies as will be required.

X (1) Studies are ongoing,

___ (2) Protocols were submitted and approved.

___ (3) Protocols were submitted and are under review.

___ (4) If no protocol has been submitted, attach memo describing status of discussions.

___ d. If the sponsor is not willing to do pediatric studies, attach copies of FDA's written request that such studies be done and of the sponsor's written response to that request.

___ 4. **PEDIATRIC STUDIES ARE NOT NEEDED.** The drug/biologic product has little potential for use in pediatric patients. Attach memo explaining why pediatric studies are not needed.

___ 5. **If none of the above apply**, attach an explanation, as necessary.

ATTACH AN EXPLANATION FOR ANY OF THE FOREGOING ITEMS, AS NECESSARY.

/S/ Regulatory Management Officer 10-7-99

Signature of Preparer and Title Date

cc: Orig NDA/PLA/PMA # 20-778/20-779
Div File
NDA/PLA Action Package
HFD-006/ SOlmstead (plus, for CDER/CBER APs and AEs, copy of action letter and labeling)

Section 16. Debarment Certification.

Applicant has reviewed a published list of persons who have received debarment notices or have been debarred under subsection (a) or (b) of Section 306 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 335a(a),(b)) from activities regulated by the Food and Drug Administration (the list, dated September 28, 1998, was obtained through the FDA's Internet website http://www.fda.gov/ora/compliance_ref/debar/debar.txt). Agouron has not found in such list the name of any person (including any individual who is an Agouron employee, key contract personnel, or clinical investigator listed in Section 8A, or any corporation, partnership, or association) performing any service associated with this supplemental application who is a debarred person. Accordingly, pursuant to Section 306(k) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 335a(k)), the undersigned hereby certifies that Agouron did not and will not use in any capacity the services of any person debarred under Section 306 of the Federal Food, Drug, and Cosmetic Act in connection with this application.

Connie J. Kohne

Connie J. Kohne
Director, Regulatory Affairs
Agouron Pharmaceuticals, Inc.

1/19/99
Date

Section 16. Debarment Certification.

Applicant has reviewed a published list of persons who have received debarment notices or have been debarred under subsection (a) or (b) of Section 306 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 335a(a),(b)) from activities regulated by the Food and Drug Administration (the list, dated September 28, 1998, was obtained through the FDA's Internet website http://www.fda.gov/ora/compliance_ref/debar/debar.txt). Agouron has not found in such list the name of any person (including any individual who is an Agouron employee, key contract personnel, or clinical investigator listed in Section 8A, or any corporation, partnership, or association) performing any service associated with this supplemental application who is a debarred person. Accordingly, pursuant to Section 306(k) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 335a(k)), the undersigned hereby certifies that Agouron did not and will not use in any capacity the services of any person debarred under Section 306 of the Federal Food, Drug, and Cosmetic Act in connection with this application.

Connie J. Kohne

Connie J. Kohne
Director, Regulatory Affairs
Agouron Pharmaceuticals, Inc.

1/19/99
Date

Section 14. Patent Certification under 21 U.S.C. § 355(b)(2)(iii).

Pursuant to the provisions of Section 505(b)(2) of the Federal Food, Drug and Cosmetic Act [21 U.S.C. § 355(b)(2)], insofar as this application relies for approval on any investigations described at 21 U.S.C. § 355(b)(1)(A) that were not conducted by or for Agouron, and for which Agouron has not obtained a right of reference or use from the person by or for whom the investigations were conducted: the undersigned certifies that, to the best of her knowledge and in the opinion of applicant with respect to Patent No. 5,484,926, which claims the drug for which such investigations were conducted and for which information is provided above as required by 21 U.S.C. § 355(b)(1), such patent will expire on October 7, 2013.

Connie J. Kohne

Connie J. Kohne
Director, Regulatory Affairs
Agouron Pharmaceuticals, Inc.

1/19/99
Date

Section 14. Patent Certification under 21 U.S.C. § 355(b)(2)(iii).

Pursuant to the provisions of Section 505(b)(2) of the Federal Food, Drug and Cosmetic Act [21 U.S.C. § 355(b)(2)], insofar as this application relies for approval on any investigations described at 21 U.S.C. § 355(b)(1)(A) that were not conducted by or for Agouron, and for which Agouron has not obtained a right of reference or use from the person by or for whom the investigations were conducted: the undersigned certifies that, to the best of her knowledge and in the opinion of applicant with respect to Patent No. 5,484,926, which claims the drug for which such investigations were conducted and for which information is provided above as required by 21 U.S.C. § 355(b)(1), such patent will expire on October 7, 2013.

Connie J. Kohne

Connie J. Kohne
Director, Regulatory Affairs
Agouron Pharmaceuticals, Inc.

1/19/99
Date

HFD-530/KELLY

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Division of Antiviral Drug Products
Food and Drug Administration
Rockville MD 20857

Record of Teleconference

NDA: **20-778 and 20-779**

Date: **March 2, 1999**

Drug: **Nelfinavir**

Sponsor: **Agouron**

BETWEEN: **Representatives of Agouron**
Connie Kohne, Director Regulatory Affairs
Barry Quart, Regulatory Affairs
Mark Decker
Yueh Chang
Merrill Gersten
Amy Hendricks
Brad Kerr
Linda Paradiso
Tom Thayer
Annkatrin Petersen

AND: **Representatives of DAVDP**
Jeff Murray, M.D., M.P.H. Team Leader
Teresa Wu, M.D., Ph.D., Medical Officer
Katie Laessig, M.D., Medical Reviewer
Kellie Reynolds, Pharm.D., Biopharmaceutical Team Leader
Christine Kelly, RN, MS, MBA, Project Manager

SUBJECT: Dissolution of Crushed Tablets, Pediatric Exclusivity, and Traditional Approval

Background: This teleconference was requested by the Medical Officer (2/26/99) to discuss dissolution of crushed tablets, pediatric exclusivity, and traditional approval. This is in reference to the sponsor's supplements [redacted] N20-778/SE2-011, and N20-779/SE2-022.

Discussion:

Re: Crushed Tablets

1. Agouron will provide individual data from their dissolution studies for the [redacted] tablet.
2. Agouron agreed to change the wording in the proposed labeling to include information about rinsing the cup. FDA will provide proposed wording to the sponsor.

Re: Pediatric Exclusivity

3. FDA suggested to the sponsor that they perform one year follow-up (at least) on HIV infected infants from the maternal transmission study. Agouron expressed difficulty in complying with this request because the transmission study (ACTG 353) is conducted and monitored by the ACTG. However, Agouron has agreed to strive for obtaining 1-year follow-up safety data, albeit incomplete.

4. Agouron clarified the distribution of the patients by their ages.

Re: Traditional Approval Package

5. It was agreed upon that Agouron will submit the following study reports for traditional approval, after filing of the supplement, but prior to July 1999: 511, Avanti, 364, CPCRA045, and 506.

6. Agouron will provide a timeline for the submission of their pediatric study reports prior to the March 10, 1999, filing meeting.

Concurrence:
HFD-530/TL/J.Murray/ 3-3-99
HFD-530/MO/Wu/3-3-99
HFD-530/BP TL/Reynolds/3-2-99

cc:
NDA 20778, 20779
Division File
HFD-530/TL/J.Murray without faxes
HFD-530/MO/Wu "
HFD-725/Stat TL/P.Flyer "
HFD-725/Stat/M.Elashoff "
HFD-530/CSO/Kelly "
HFD-530/BP TL/Reynolds "
HFD-530/BP/Gillespie "

APPEARS THIS WAY
ON ORIGINAL

Record of Teleconference

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Division of Antiviral Drug Products
Food and Drug Administration
Rockville MD 20857

Record of Teleconference

NDA: **20-778/SE2-11 and 20-779/SE2-22**

Date: **October 15, 1999**

Drug: **Viracept® (nelfinavir)**

Sponsor: **Agouron**

BETWEEN: **Representatives of Agouron**
Connie Kohne, Director Regulatory Affairs
Barry Quart, Regulatory Affairs
Yueh Chang, Statistician
Karen Cormier, Statistician
Poe-Hirr Hsyu, Biopharmaceutics
Bill Paxton, Medical Monitor

AND: **Representatives of DAVDP**
Jeff Murray, M.D., M.P.H. Team Leader
Teresa Wu, M.D., Medical Reviewer
Katie Laessig, M.D., Medical Reviewer
Girish Aras, Ph.D., Statistical Team Leader
Tom Hammerstrom, Ph.D., Statistical Reviewer
Sylvia Lynche, Pharm.D., Regulatory Project Manager

Background: This teleconference was requested by DAVDP to discuss an algorithm for defining virologic treatment failures in Agouron studies (please reference the June 16, 1999 facsimile to Agouron).

Discussion:

1. The teleconference commenced with Dr. Wu providing the agenda for discussion as follows:
   a. Referencing the June 16, 1999 statistical comments regarding studies 542, 511, and 506.
   b. Dr. Hammerstrom giving his analysis on rules for failure in these studies.
   c. Dr. Laessig commenting on data analysis for study 506.

2. Dr. Hammerstrom listed rules for defining virologic failure in his analysis of study 542. There was some discussion regarding the value of an analysis in which the rules for treatment failure would be applied differently for the bid and tid treatments, such that discontinuations for toxicity would be censored on the tid arm and counted as failures on the bid arm. The division commented that this analysis would not be used for labeling but could be conducted as a sensitivity analysis, given that the study design was open-label.

3. Dr Laessig informed Agouron that for study 506 they could leave the data at 24 weeks instead of 48 weeks because of the protocol amendment which allowed treatment switches. Agouron agreed with this comment.

Action Item:

1. Agouron will submit a reiteration of the rules for failure in analyzing tid to bid dosing.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Division of Antiviral Drug Products
Food and Drug Administration
Rockville MD 20857

Record of Teleconference

NDA: **20-778/SE2-11 and 20-779/SE2-22**

Date: **November 5, 1999**

Drug: **Viracept® (nelfinavir)**

Sponsor: **Agouron**

BETWEEN: **Representatives of Agouron**
Patricia Rizun, Senior Regulatory Affairs Specialist
Barry Quart, Pharm.D., Head of Drug Development
Yueh Chang, Statistician
Neil Clendeninn, Vice President Clinical Affairs
Mike Adam, Director of regulatory Affairs

AND: **Representatives of DAVDP**
Jeff Murray, M.D., M.P.H. Team Leader
Teresa Wu, M.D., Medical Reviewer
Katie Laessig, M.D., Medical Reviewer
Girish Aras, Ph.D., Statistical Team Leader
Tom Hammerstrom, Ph.D., Statistical Reviewer
Michael Elashoff, Ph.D., Statistical Reviewer
Sylvia Lynche, Pharm.D., Regulatory Project Manager

Background: This teleconference was requested by Agouron to discuss labeling changes to the September 23, 1999 draft Viracept Package Insert (please reference the October 21, 1999 facsimile to Agouron).

Discussion:

1. The teleconference opened with Dr. Quart requesting that the discussion follow the issues raised in the October 21, 1999 facsimile from DAVDP in regards to changes to the September 23, 1999 draft Viracept package insert label.

2. Dr. Elashoff provided rationale for using Kaplan Meier(KM) curves in labels to show results of 48 week studies:

- The KM curve uses all data from the studies.
- The KM curve estimate reflects how the studies are conducted and gives a time when treatment stops working.
- The KM curve allows one to estimate median duration of response and accounts for censoring.

3. Agouron agreed with the rationale for using the KM curve, but had concerns the KM curve will not be understood in the community.

4. DAVDP is recommending that all labels describing studies with 48 week data include a KM curve and a table that shows proportions of patients with HIV RNA < then assay limit, above the assay limit and proportions of patients who discontinued or experience a class C event. In the sponsor's advertisements the KM curve would not have to be shown. In addition the sponsor would also be permitted, during this transition, to include curves showing proportions below as assay limit at study time points.

5. DAVDP agreed with Agouron to use 24 week safety data for study 511 since many patients on placebo may have switched to nelfinavir after 24 weeks of treatment.

6. Agouron stated concerns with the wording of the Viagra interaction in the package insert and recommended the following wording be changed to [redacted], including Viracept [redacted]'
DAVDP agreed that Agouron could use this proposed wording.

7. DAVDP stated the Microbiology reviewer would reword line 82 of the package insert.

8. In closing Agouron stated that they would look at data to support the resistance issue. They know they can support a > 50% response rate, but not able to support a randomized controlled study data.

Action Items:

1. Agouron agreed to keep KM curves, proportion below assay limit curves and a table showing proportions below assay limits and discontinuations in the package insert. For traditional approval the proportion below the assay limit curves may be removed.

2. Microbiology reviewer will revised line 82 of the package insert.

Concurrence:

Appl_key: N020779

DRUG_NAM VIRACEPT (NELFI **SPONSOR:** AGOURON

User: lynches **Date:** 1/16/99 3:42:19 PM **Contacted:** Mark Longer

This telecon was requested by the Chemistry review team. It was to discuss SCF-27 (film coating supplement).

FDA participants: George Lunn, Teresa Wu, Sylvia Lynche
Agouron participant: Mark Longer

Action Items:

Agouron will incorporate the film-coated tablet description in to the package insert that also describes the 270 and 300 count bottles. Tentatively they will put "Keep container tightly closed" in bold in the HOW SUPPLIED section. However, they will not submit this version until they receive a fax containing other comments that Dr. Wu will send to them.

Agouron will send us by FedEx a color copy of the current bottle label so we can discuss how to add "Keep container tightly closed" and "Dispense in the original container".

Agouron dose not yet have a finalcopy of the 300 count bottle label but it will be identical to the 270 count label except for the number. There will be no additional material (e.g., "For BID regimen").